Remarks

I. Claims Status

Claims 1-16 are pending.

Claims 1-15 are rejected.

Claim 16 is objected to.

Claims 1-16 are canceled.

Originally filed claims 1-36 are reintroduced.

II. Background

The instant application was originally filed as a PCT application with 36 claims. The claims were amended to the pending claims 1-16 in view of the PCT Written Opinion, which indicated, among other things, that the originally filed claims did not present searchable subject matter, i.e., diagnostic or therapeutic method claims. In its response to the PCT Notification mailed to applicant on June 29, 2004, applicant stated that it reserved the right to revert to any subject matter originally claimed and/or disclosed. Based on the Rules of US patent practice, applicant now requests that pending claims 1-16 be canceled without prejudice and replaced by the original PCT-filed claims 1-36 appearing on the attached sheets entitled Amended Claims.

Applicant respectfully submits that the amended claims are literally directed to subject matter directly set forth in the summary of the invention and as described in the specification. The methods set forth in claims 1-27, as well as the device readable medium recited in claims 28-36, are closely associated with the pending claims 1-16. For example, the *means for controlling the apparatus to deliver a myopia correcting nominal laser ablation in an optical zone identified for the myopia correcting nominal ablation of an exposed corneal surface of an eye, characterized in that the apparatus is further controlled to deliver a laser ablation in a region outside of the identified optical zone so as to create a central flattening of the corneal surface via a controlled biodynamic response to the exposed corneal surface outside of the identified optical zone*, recited in pending claim 1, essentially is the method and the executable instruction as set forth in new claims 1-36. As such, the nature of the claimed subject matter is not materially different than that of the pending claims.

Notwithstanding the new claims, applicant believes that the examiner would still have raised claim objections under 35 USC 102(e) in view of Ruiz US 6,302,877. Applicant therefore respectfully provides the comments below in prospective traverse of the examiner's rejection.

III. Applicant's Invention

Applicant's claim 1 describes *a method for laser vision correction, comprising providing a controlled biodynamic response in corneal tissue of an eye by inflicting a controlled trauma to an exposed corneal surface outside an identified optical zone for a myopia correcting nominal laser ablation of the cornea.* The method is further characterized as delivering a stromal ablation in a region outside of the identified optical zone so as to

create a central stromal flattening *via* a controlled biodynamic response to the stromal ablation outside of the identified optical zone.

As is well known, myopia correction requires that the central region of the cornea be flattened or made less bullet-shaped because, in the case of myopia, the eye is too strongly focusing light in front of the retina. As clearly pointed out by Applicant, the correction of myopia requires the central corneal region to be flattened. Flattening the cornea requires removal of stromal volume in the central region of the cornea relative to the peripheral region of the cornea. It is well known that the amount of tissue that can be removed is limited by the residual (post-operative) thickness of the cornea. It is also widely suspected that when the centralized ablation is carried out over a region of the cornea that is smaller than the subject's optical zone, that patients experience glare, halos and other vision defects notwithstanding the correction of their myopia. Often, however, ablation over the full optical zone identified for myopia correction will result in the removal of so much tissue volume that the residual corneal thickness is less than the safe limit. Applicant's invention addresses this problem.

An appreciation of Applicant's claimed invention requires an understanding of what is meant by the term *optical zone* as used therein. The *optical zone* is understood in the art to be the pupil-delimited region through which object light is directed to the back of the eye to form an image on the retina. The optical zone cannot be larger than the pupil diameter, however, the optical zone size will be different for a dilated pupil and an undilated pupil. If a myopia correcting ablation is performed on an undilated eye pupil, the optical zone will be small (typically 3-3.5 mm diameter or less). Under low-light conditions, e.g., night time, the pupil

will dilate and the optical zone will increase in size, typically to between 7-8 mm or larger. As mentioned above, failure to perform ablation over a large enough optical zone may result in annoying vision problems when the pupil dilates and the optical zone becomes larger than that over which the ablation was performed. Applicant's claimed invention requires less stroma to be ablated over a larger optical zone. This is achieved, as set forth in claim 1, by *providing a controlled biodynamic response in corneal tissue of an eye by inflicting a controlled trauma to an exposed corneal surface outside of an identified optical zone for a myopia correcting nominal laser ablation of the cornea.* The removal of stromal material outside of this optical zone that has been identified as the zone necessary to correct the patient's myopia has the dual benefit of avoiding deep ablation within the optical zone (the light transmitting region of the cornea), and physically flattening the central region of the cornea *via* the biodynamic response of the eye to the controlled ablation outside of the identified optical zone. Since the eye is biodynamically flattened, the amount of tissue that must be removed in the nominal ablation procedure to correct the myopia (to further flatten the cornea) is less than the amount of tissue within the optical zone that would need to be removed absent the biodynamic flattening of the cornea.

IV. Ruiz US 6,302,877

Ruiz '877 is primarily concerned with the correction of presbyopia; i.e., the inability of the eye to accommodate such that the eye's optics can focus an "optically near" object as well as an "optically far" object. For an optically near object, the eye must bend light more strongly to create a focused image on the retina than for an optically far object. Therefore, for the typical presbyope, the near vision is hyperopic, i.e., the light is coming to a focus behind the retina rather than in front of the retina due to a lack of refracting power.

According to Ruiz '877, the ablation by an annular ring outside of a small central region of the cornea *produces a central protrusion of the stroma such that when the corneal flap is repositioned at its initial position, this stromal curvature change is transmitted to the forward corneal surface, thereby indirectly transforming the corneal surface into a multifocal surface, which is, in fact, myopic in its central part* (*see* Column 11, lines 7-23). In other words, the Ruiz ablation has induced a myopic condition by making the central region of the cornea more bullet-shaped so that the light rays can be bent more strongly by this small central region of the cornea, thus helping to focus optically near objects. Central corneal flattening has not been disclosed.

In contrast to Applicant's invention, Ruiz '877 proposes a system arranged to obtain an *annular shaped ablation within a corneal area which is not used for far sight* (*see* Column 12, line 66 to Column 13, line 2). Since Ruiz '877 is concerned with presbyopia correction requiring the maintenance of both near vision and far vision, at least two distinct focusing zones must be established within the optical zone of the subject's eye. Ruiz '877 does this by masking a central corneal region of between about 1-3mm and ablating the stroma in an annulus adjacent the masked region. Ruiz refers to the masked region as the optical zone (*see* Column 13, lines 33-34). The masked region becomes that portion of the overall optical zone that serves for near distance viewing due to its increased curvature, while a more peripheral region of the light transmitting portion (i.e., optical zone) of the subject's cornea is used for far distance viewing. The two regions are delineated by the annular ablation that has been performed around the very small centralized region of the subject's eye, thus forming two zonal regions within the patient's overall optical zone.

Ruiz '877 does not disclose *a controlled stromal ablation in a region outside of the optical zone identified for a myopia correcting nominal ablation so as to create a central stromal flattening, via a controlled biodynamic response* (or otherwise). Applicant reiterates that the suggested procedure in Ruiz '877 actually induces myopia in their 'defined' optical zone for increasing focusing power.

Applicant respectfully requests the Examiner's reconsideration of the application. No extension of time is necessary to make this Amendment timely. Should applicant be in error, applicant respectfully requests that the Office grant such time extension pursuant to 37 C.F.R. §1.136(a) as necessary to make this Amendment timely, and hereby authorizes the Office to charge any necessary fee or surcharge with respect to said time extension to the deposit account of the undersigned firm of attorneys, Deposit Account 50-1546.

Respectfully submitted,

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